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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,968	04/07/2000	Lloyd S. Gray	12582	1109

7590 05/07/2002
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EXAMINER

COVINGTON, RAYMOND K

ART UNIT PAPER NUMBER

1625

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/544,968

Applicant(s)

Gray et al

Examiner

Raymond Covington

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/11/01
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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Applicants' comments have been noted and considered with the following effect.

The election of species requirement under 35 USC 121 is maintained. However, the scope of the generic concept embraced by that species has been expanded to exclude other related species that would also render the elected species obvious and therefore unpatentable. Accordingly, claims 1-59 are pending and will be considered too the extent they read on the elected species and it's generic concept.

Claims 42-48 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cancer, does not reasonably provide enablement for treating **all cancers**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. For example, the cancer therapy art remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, 8, 14-18, 27, 40, 46, 49, 50, 52 and 53 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Hackh's Chemical dictionary.

Hackh's Chemical dictionary teaches the simplest species embraced by applicant's claims, e.g. furan, thiophene, pyrrole, pyrazole, imidazole, oxazole, thiazole, pyran, thiopyran, morpholine, thiazine, piperazine, piperidine, indole, quinoline etc. as well as the well-known substituents thereto.

Claims 1-41, 49, 50 and 52-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hackh's Chemical dictionary. Hackh's Chemical dictionary is applied as in the next above 102 rejection. Claims 2-6, 9-13, 19-26, 28-39, 41, 43-45, 47, 51 and 54-59 are rejected as depending upon a rejected base claim. As to specific recited species unexemplified in the reference it is noted that A reference must be considered in its entirety and is not limited to specific working examples contained in it; reference patent is prior art not only for teaching of specific embodiment recited, but for what it fairly teaches to one skilled in the art. While the art teachings relied upon were phrased in terms of a non-preferred embodiment or as being unsatisfactory for the intended purpose the disclosures must still be evaluated for what they fairly teach one of ordinary skill in the art. Disclosed examples and preferred embodiments do not

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constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971).

Claims 1-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for derivatives containing the 5 member N- heterocyclic moiety, does not reasonably provide enablement for derivatives drawn to the vast range of heterocyclic containing derivatives, particularly, for example, cinoline derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. There is insufficient enabling disclosure to support the terms heterocyclyl R, X, R₃, R₄, R₅.

Claims 1-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

The specification does not give any guidance as to how each of the heterocyclic substituted derivatives were prepared. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,

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5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.


Claims limiting the scope of these terms to the 5 member N-heterocyclic elected species and related compounds should overcome this rejection.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (703)308-4704.


rk

April 26, 2002


ALAN L. ROTMAN
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